Comments from USCG on Gulf Study Version 07 Sept 2010 for IOM meeting

On page 15 Active Cohort:
The statement that "active cohort may be largely restricted to persons residing in Gulf States" is likely based on the NIOSH roster. However, many CG personnel will be from out of that area, so the proportion of non Gulf States people included in the cohort will depend to some degree on what proportion of CG personnel we think may end up in the study. For example, if there end up being say 2,000 CG/exposed participants out of an estimated 27,000, that's 7% of the cohort, so the above statement might not be too accurate. (Minor point, though)
On page 16 Active Cohort – controls:
Regarding those CG personnel eligible to go but who didn't end up responding: we could argue that all CG personnel fit for duty would have been eligible. So, potentially the entire non-responder Coast Guard could be the catchment for all CG controls (or some proportion of federal controls). We may want to have non-exposed/controls from CG selected based on the distribution of reserves/active duty/civilians who are included in the exposed group, just to make sure that controls are similar to exposed CG participants in all respects other than exposure (ie, we wouldn't want all the controls to be active duty).
Flowchart on page 9
Counts of non-exposed federal workers would be 2,000, but also non-local controls would be 1,000. We should assume that most federal workers will be non-local also, so is that what the investigators are intending? Does that need to be clarified? Depending on the definition of non-exposed for CG, we could actually have a huge catchment of non-exposed, as described above.
Informed Consent Form
The informed consent form describes that those who consent will have a home visit of 2.5 hours which will include collection of bio-specimens. Does that mean ALL who consent will have the home visit? We thought that the collection of bio-specimens would occur on just a sub-set of the population - though the flow chart indicates that bio-specimens would be collected on all (or are we reading it incorrectly?)
The informed consent wording may be confusing to some CG members regarding eligibility, ie, the 5 states residency criteria (4^{th} bullet) OR the CG worker status (5^{th} bullet). It might get a little confusing about the issue of federal workers (ie, CG) residing in the 5 Gulf States. So, our possible CG exposed group would consist of those CG people who responded to the oil spill AND all those CG people who did or did not respond to oil spill, but live in one of those 5 states. Is that what the investigators intended?

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The material you just sent has very nicely fleshed out important details of the study design and general methodology.

My personal opinions, merely outlined here until we decide whether and how you want them spelled out as brief review, are as follows:

- Overall, the study design is sound and informative (I like the concept a lot). Many strengths, not listed here, in terms of the science and efficient study design.

- Concerns that emerge from a quick reading is the potential pitfall of introducing a different profile of health and risk characteristics in the Unexposed Group, if the former are associated with their being excluded from clean up-related work.

- Minimal characterization of the non-participants is highly desirable, to enable calibration / sensitivity analyses of min results and estimates of population impact.

- Widening the scope of the surveillance to morbidities beyond malignancies and events other than deaths also seems necessary to make this informative (the cancer and fatal outcomes likely to be delayed, and only the tip of the putative burden of morbidity).

- Consider simple and low-cost, regional "community surveillance" of affected areas to capture community impact and adverse effects beyond those in the typically healthy and robust individuals actively engaged in clean up operations of various kinds, inclusive of reproductive effects, admissions for respiratory conditions, and such.

- The success of the study will evidently be critically dependent on experienced agencies that can coordinate and support the timely and standardized acquisition of data in the field and its management. Proactive and nimble quality assurance will be essential given the operational complexity of the study and its time line. This is not yet addressed in the materials shared.